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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

MERLE KOVTUN, Individually And On Behalf Of All Others Similarly Situated,

Plaintiff,

vs.

VIVUS, INC., LELAND F. WILSON, and WESLEY W. DAY PH.D.,

Defendants.

Case No. CV 10- 4957 PJH

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiff alleges the following against Vivus, Inc. ("Vivus" or the "Company") and the other Defendants as defined, *infra* ¶ 19, based upon the investigation of Plaintiff's counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by Vivus, securities analysts reports and advisories about the Company, press releases issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth below after a reasonable opportunity for discovery.

NATURE OF THE ACTION AND SUMMARY OF ALLEGATIONS

1. This is a securities class action on behalf of all persons who purchased or otherwise acquired the common stock of Vivus between September 9, 2009, and July 15, 2010, inclusive (the "Class Period"), against Vivus and certain of its officers and/or directors for violations of the Securities Exchange Act of 1934 (the "Exchange Act").

2. Vivus is a biopharmaceutical company that develops therapies to address obesity, sleep apnea, diabetes, and male sexual health. The Company develops and commercializes therapeutic products for large underserved markets and currently has one FDA-approved drug on the market, MUSE®, a prescription treatment for erectile dysfunction. The Company also has several investigational product candidates in late stages of clinical development that are focused on market opportunities in obesity and related morbidities, including sleep apnea and diabetes, and sexual health where the potential worldwide pharmaceutical market could approach billions. The Company's lead product in clinical development is Qnexa® ("Qnexa" or the "drug"), an experimental drug that has completed Phase III clinical trials for the treatment of obesity. In December 2009, Vivus submitted a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") to have Qnexa approved as an obesity drug. On March 1, 2010, the FDA accepted the NDA filing for review.

3. During the Class Period, Vivus issued materially false and misleading statements to the investing public regarding Qnexa. Vivus continuously hyped Qnexa's "remarkable safety," and its potential for success via NDA approval, while materially understating the health

risks associated with the drug. As a result of Vivus's false statements, the Company's stock traded at artificially inflated prices during the Class Period, reaching a high of $13.68 per share on May 18, 2010.

4. On July 15, 2010, the Endocrinologic and Metabolic Drugs Advisory Committee of the FDA (the "FDA Panel") composed of independent medical experts whose recommendations carry great weight within the FDA approval process, voted 10 to 6 against the approval of Qnexa based upon an "overall risk-benefit assessment" for use in obese individuals and certain overweight patients with other health problems such as diabetes or high blood pressure.[1] Even some of the panel members who voted "yes" noted that it was "a very fine line between a yes and a no vote," and that they could have voted no.

5. The FDA Panel members who voted "no" cited "serious" and "life-threatening" side effects in Qnexa's trial data, including birth defects, depression, anxiety, sleep disorders, cognitive disorders, metabolic acidosis (too much acid in the body fluids), and an unknown impact on the heart as reasons they could not recommend the drug's approval.

6. The FDA Panel refused to recommend Qnexa as a chronic or "lifetime" drug therapy because the limited data made it "difficult if not impossible" to weigh the long-term safety of the drug. Only 56 weeks of safety data were provided from the clinical studies even though, if approved, the expected time frame for Qnexa use would be much longer since obesity is a "chronic disease requiring chronic treatment." According to Dr. Lamont G. Weide, a voting panel member and endocrinologist at the University of Missouri, Kansas City, "[t]he real question is when we look at this drug is how safe it is and for how long because this is likely a lifetime therapy." Dr. Weide also specifically stated, "I feel uncomfortable with a year's worth

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[1] The sixteen voting FDA Panel members included: Dr. Thomas P. Bersot, Dr. David M. Capuzzi, Dr. Allison B. Goldfine, Dr. Abraham Thomas, Dr. Lamont G. Weide, Dr. Elaine H. Morrato, Dr. Sanjay Kaul, Dr. Kenneth D. Burman, Dr. Susan R. Heckbert, Dr. Katherine M. Flegal, Dr. Jessica W. Henderson, Dr. Janet D. Cragan, Ms. Melanie Coffin, Dr. Ed J. Hendricks, Dr. Michael A. Proschan, and Dr. Michael A. Rogawski.

of data." Other FDA Panel members indicated that chronic use would likely require longer-term studies of approximately five years.[2]

7. Vivus investors were not aware of Qnexa's "serious" and "life-threatening" health risks, or the inadequacy of the clinical data, prior to the FDA Panel's July 15, 2010 vote. When news of the vote was publicly announced on July 15, 2010, the market price of Vivus common stock plummeted, falling $6.70 per share, or 55%, in one day on unusually high trading volume of over 42.3 million shares.

8. The true facts, which were known by the Defendants during the Class Period, but concealed from the investing public with repeated and express assurances of the drug's safety profile, were as follows:

(a) the studies conducted by Vivus and submitted to the FDA Panel could not support FDA Panel approval for Qnexa's use to treat obesity as a chronic condition, and, at the very least, longer-term clinical studies would be needed to determine whether Qnexa was safe for its intended use to treat chronic obesity;

(b) the trial results showed worrisome adverse effects of the type that scuttled approval for other obesity drugs, including: increased risk of suicide, cardiovascular events, and birth defects;

(c) four to seven times as many patients taking the highest dose of Qnexa, compared to patients taking lower doses or placebos, dropped out of the study because of adverse side effects such as anxiety, sleep disorders, or depression.

(d) Qnexa would likely receive a "Pregnancy Category X" label from the FDA due to birth defects (teratogenicity) risk, instead of the proposed "Pregnancy Category C" label, thereby potentially eliminating a huge swath of potential Qnexa customers.

9. Instead of revealing the serious risks revealed by the study data, Defendants repeatedly touted Qnexa's safety profile. As a result of Defendants' false and misleading

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[2] *See infra* ¶¶ 67-68.

statements, Vivus's stock traded at artificially inflated prices during the Class Period. Such inflated stock prices permitted top Vivus officers/directors to sell shares of their Company stock at inflated prices for proceeds of over $3.6 million. However, after the above adverse news was revealed to the market, the Company's share price declined dramatically.

10. On October 28, 2010, the FDA officially denied Vivus's NDA for Qnexa, as recommended by the FDA Panel on July 15, 2010. In the FDA's Complete Response Letter that set forth the reasons Qnexa was rejected, the FDA asked Vivus to provide a thorough evaluation of the drug's potential for causing birth defects and heart problems. Specifically, the FDA requested that Vivus provide a detailed plan and strategy to evaluate and mitigate the potential teratogenic (birth defect) risks in women of childbearing potential taking the drug for the treatment of obesity; and to provide evidence that the elevation in heart rate associated with phentermine/topiramate does not increase the risk for major adverse cardiovascular events. Additionally, the FDA requested that VIVUS formally submit the results from the SEQUEL study (which Vivus announced was completed on September 21, 2010), a 52-week extension study for a subset of 675 patients who completed the previously reported 56-week CONQUER study. Finally, the FDA reserved the right to comment further on proposed labeling.

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j (b) and 78t (a)], and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission [17 C.F.R. § 240.10b-5].

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act.

13. Venue is proper in this District pursuant to Section 27 of the 1934 Act and 28 U.S.C. § 1391(b). Many of the acts charged herein occurred in substantial part in this District, and Vivus conducts business in this District at 1172 Castro Street, Mountain View, CA 94040.

14. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the NASDAQ.

PARTIES

15. Plaintiff, Merle Kovtun, as set forth in the accompanying certification, incorporated by reference herein, purchased the common stock of Vivus at artificially inflated prices during the Class Period and has been damaged thereby.

16. Defendant Vivus was founded and incorporated in California on April 16, 1991, and completed a re-incorporation in the state of Delaware in May 1996. The Company's headquarters are located at 1172 Castro Street, Mountain View, CA 94040.

17. Defendant Leland F. Wilson ("Wilson") has served as Vivus's Chief Executive Officer ("CEO") since 1991 and throughout the Class Period.

18. Defendant Wesley W. Day, Ph.D. ("Day") served as Vivus's Vice President, clinical development since 2005 and throughout the Class Period.

19. Wilson and Day are referred to herein as the "Individual Defendants." Vivus, Wilson, and Day are referred to herein collectively, as the "Defendants."

20. During the Class Period, the Individual Defendants, as senior executive officers and/or directors of Vivus, were privy to confidential and proprietary information concerning Vivus, its operations, products, including the safety of Vivus's key drug Qnexa, finances, financial condition, and present and future business prospects. The Individual Defendants also had access to material adverse non-public information concerning Vivus, as discussed in detail below. Because of their positions with Vivus, the Individual Defendants had access to non-public information about its business, finances, products, including the safety of Vivus's key drug Qnexa, markets, and present and future business prospects, via access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at management and board of directors meetings and committees thereof and via reports and other information provided to them in connection therewith. Because of their

possession of such information, the Individual Defendants knew or recklessly disregarded the fact that adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

21. The Individual Defendants are liable as direct participants in, and as co-conspirators, with respect to the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors were "controlling persons" within the meaning of Section 20 of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Vivus's business.

22. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to securities analysts and, through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading, prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to, and did, commit the fraudulent acts alleged herein.

23. As senior executive officers and/or directors and as controlling persons of a publicly-traded company whose common stock was, and continues to be, registered with the SEC pursuant to the Exchange Act, trades on the NASDAQ Global Market under the ticker symbol "VVUS," the Individual Defendants were, and continue to be, governed by the federal securities laws, and had a duty to disseminate promptly accurate and truthful information with respect to Vivus's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings, and present and future business prospects; and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Vivus's common stock would be based upon truthful and accurate

information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

24. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Vivus common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Vivus's business, operations and management, and the intrinsic value of Vivus common stock, and (ii) caused Plaintiff and members of the Class to purchase Vivus common stock at artificially inflated prices.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

25. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Vivus common stock during the Class Period (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

26. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Vivus had more than 81 million shares of common stock outstanding that were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Vivus or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

27. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

28. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

29. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations, products, and financial statements of Vivus;

(c) whether Defendants omitted and/or misrepresented material facts;

(d) whether Defendants' statements omitted material facts necessary to make the statements, in light of the circumstances under which they were made, not misleading;

(e) whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(f) whether the price of Vivus common stock was artificially inflated; and

(g) the extent of damage sustained by Class members and the appropriate measure of damages.

30. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

BACKGROUND

31. With the rise of obesity in the U.S., many drug manufacturers are racing to obtain approval for their appetite suppressing weight loss drugs, so that these drugs can be marketed to

the masses for long-term use. A weight loss drug that wins regulatory approval could bring in billions of dollars a year. However, weight loss drugs that have reached the market or gotten to the final stage of FDA vetting have repeatedly been hammered by side effects and safety issues. Such is the case with Vivus's proposed obesity drug treatment, Qnexa, which completed the pivotal Phase 3 clinical trial program, including the EQUATE, EQUIP, and CONQUER studies.

32. Qnexa is an appetite suppressant that is a blend of two separate, already existing, medications: phentermine (also known under the brand names Adipex-P, Atti Plex P, Fastin, etc.), and topiramate (also known under the brand names Topamax, and Topiragen). Phentermine is FDA-approved and has been used for many years as a successful short-term weight loss formula, notwithstanding the drug's association with the infamous *Fen-Phen* weight-loss drug that was shown to cause potentially fatal pulmonary hypertension and heart valve problems, and eventually led to the drug's withdrawal and legal damages of over $13 billion for drug manufacturer Wyeth. Topiramate has also been approved by the FDA and has been used for years as an anticonvulsant to treat epilepsy and has also been used to treat migraine headaches or as an antidepressant, but also has a history of negative side effects. Qnexa essentially combines these two pre-existing drugs into a single experimental drug for targeted long-term weight loss. Ever since the *Fen-Phen* fiasco mentioned above, anti-obesity drugs reviewed by the FDA have faced strong scrutiny. Most anti-obesity drugs have failed to obtain FDA-approval for the same safety issues highlighted by the FDA Panel in voting against recommending Qnexa, as described below:

- In 2008, Merck & Co. and Pfizer Inc. stopped testing two obesity drugs under development after Sanofi-Aventis SA abandoned efforts to get FDA approval for its obesity pill *Acomplia*, which was linked to depression.
- In early October 2010, the FDA pressured drug manufacturer Abbott Laboratories to take its diet drug *Meridia* off the market after a study found that the drug raised the risks of heart attacks and strokes in certain patients. *Meridia* was approved three years ago in 1997 even though an advisory committee had rejected it.

- On October 22, 2010, the FDA rejected another diet drug, Arena Pharmaceuticals's *Lorcaserin* because a study showed that the drug in high doses caused tumor formation in rats. The rejection came after an advisory committee to the FDA had voted 9 to 5 against approval in September 2010.

33. In recent years, in light of increased political sensitivity with respect to drug safety, the FDA has been raising the bar for new drug approvals, driven (at least in part) by complaints that the agency did not adequately consider safety data and by calls from Congress to stiffen standards. The painkiller *Vioxx* was voluntarily withdrawn in 2004 after safety concerns surfaced, and more recently the diabetes drug *Avandia*, which is still on the market, has been the focus of congressional inquiries and mass tort lawsuits by users of *Avandia* alleging harm from use of the drug. Both drugs, with multibillion-dollar sales at their peak, were linked to serious heart problems.

34. As Defendants knew, these past events, in which serious side effects were discovered relating to obesity drugs, have created a cautious environment that will require solid safety results before FDA approval is granted to new drugs, including Qnexa.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

35. The Class Period begins on September 9, 2009, the date when Vivus announced "outstanding" results from two Phase 3 studies it had conducted. On this date, Vivus issued a press release announcing that: (a) obese patients on Qnexa achieved average weight loss of up to 14.7% and significant improvements in co-morbidities; (b) results of EQUIP and CONQUER Phase 3 Studies exceeded FDA benchmarks for obesity treatments; and (c) demonstrated a positive safety profile. The Company's press release provided further detail regarding Qnexa's efficacy and positive safety profile, stating in relevant part that there is "no signal for suicidality risk," increased depression, or clinically significant change in overall cognitive function or effect on psychomotor skills.

36. The Company's September 9, 2009, press release stated as follows:

> MOUNTAIN VIEW, Calif., Sept 09, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- VIVUS, Inc. (Nasdaq: VVUS) today announced positive results from two final, phase 3 pivotal 56-week studies, EQUIP (OB-302) and CONQUER (OB-303), evaluating the safety and efficacy of Qnexa(TM), an investigational drug, in more than 3,750 patients across 93 sites. The EQUIP and CONQUER studies met all primary endpoints by demonstrating statistically significant weight loss with all three doses of Qnexa, as compared to placebo. Patients taking Qnexa also achieved significant improvements in cardiovascular and metabolic risk factors including blood pressure, lipid levels, and type 2 diabetes.
>
> * * *
>
> Qnexa is a proprietary formulation and unique dosing regimen that combines two well known pharmaceutical therapies - phentermine and topiramate - to create a novel, patented therapy. The phase 3 program evaluated three doses of Qnexa (numbers reflect milligrams of phentermine and controlled release topiramate, respectively):
>
> -- Qnexa 15/92 (full dose)
>
> -- Qnexa 7.5/46 (mid dose)
>
> -- Qnexa 3.75/23 (low dose)
>
> * * *
>
> Across both 56-week studies comprised of more than 3,750 patients, the most commonly reported side effects were dry mouth, tingling, constipation, altered taste and insomnia. **Monthly assessments using prospective psychometric instruments in accordance with FDA's guidance showed no signal for suicidality risk. There were no suicide attempts or suicidal behaviors, and there was no signal for suicidal ideation across all treatment groups including placebo.** Depression or depressed mood adverse events of a moderate to severe nature were less than 2% and were similar among patients in the Qnexa and placebo groups. Overall, depression scores, quality of life including self esteem and general health significantly improved for patients on Qnexa.
>
> VIVUS completed a thorough QT prolongation (TQT) study evaluating subjects taking Qnexa. The study was completed with no signal for QT prolongation. Subjects taking Qnexa also underwent complex and extensive cognitive and psychomotor testing using validated, FDA accepted testing methodologies. **There was no clinically significant change in overall cognitive function or effect on psychomotor skills seen in patients taking Qnexa.**
>
> [Emphasis added.]

37. The September 9, 2009, Vivus press release also announced that EQUIP study patients taking full-doses of Qnexa had a higher completion rate than those taking either the placebo or the low-dose of Qnexa, and CONQUER study patients taking the high-dose of Qnexa

had a higher completion rate than those taking the placebo. The September 9, 2009, Vivus press release stated, in relevant part:

> Completion rate for EQUIP was 47%, 57%, 59% for patients taking placebo, low-dose Qnexa and full-dose Qnexa, respectively.
>
> * * *
>
> Completion rates for CONQUER were 57%, 69%, 64% for patients taking placebo, mid-dose Qnexa, and full-dose Qnexa, respectively.

38. Defendant Wilson was quoted in this press release regarding Qnexa's prospects as follows:

> The results of the phase 3 program, designed and executed after Special Protocol Assessments were completed by the FDA, exceed the FDA benchmarks for clinically significant weight loss. **The results support the company's plan to file a New Drug Application with the FDA by the end of 2009 and submit the results from the studies for publication in peer-reviewed journals. We believe these results may provide a compelling opportunity for global pharmaceutical companies, and we intend to initiate partnering discussions now that we have the full data set in hand.**

[Emphasis added.]

39. Vivus also hosted an investors' conference call on September 9, 2009, to trumpet Qnexa's safety data. During the conference call Vivus CEO, Defendant Wilson, described Qnexa's safety profile as follows:

> Qnexa was well tolerated and demonstrated an excellent benefit risk profile. **Based on the efficacy and safety data that you will see we believe Qnexa meets all FDA requirements for approval.**
>
> * * *
>
> . . . [t]here was no difference in total serious adverse events between placebo and active treatment. And there was no difference in drug-related serious adverse events. **Yeah, the drug related adverse events that we saw were few and there was no pattern of any one particular item.** I would say that one of the issues that the – that does come up with these kinds of drugs and weight loss drugs in general is that **we have I think two kidney stones and one gallstone as serious adverse events in the clinical study. But that's the only one that we think is drug-related in the serious adverse event column.**
>
> * * *
>
> I think again all of you would agree that this – the studies have produced remarkable – not only remarkable efficacy, but **remarkable safety** as well. **And**

> **we've looked at this from every different perspective, at every different issue as far as safety is concerned and we have found literally no issues of concern at this point. And so I want to emphasis that very, very strongly** . . . [t]his is a very exciting time for our company and it should be a very exciting time for our investors as well.
>
> [Emphasis added.]

40. Defendant Wilson stated the following regarding dosage tolerance levels for trial patients:

> Based on what we see from the data, clearly the low-dose will be used as apart of a titration regimen which will take patients up to the middle-dose. **And then the middle-dose I think will be adequate for a majority of the patients for a significant period of time and that will allow a – the higher dose then will allow a doctor to move up if the patient is doing well and is well tolerated** but it gives them that choice to go to higher level of medicine and to – and I think the doctor can tailor this to the heavier patients that have more co-morbidities that they want to lose weight faster, those kinds of an approach. But it gives a wonderful opportunity here for a doctor to titrate into the tolerance with the individual patient.
>
> [Emphasis added.]

41. Defendant Day, Vivus's Vice President in charge of clinical development, elaborated on Qnexa's glowing safety profile and low discontinuation rate, stating, in relevant part:

> Now let's turn our attention to safety. Slide 28 presents a detailed table, which lists treatment emergent side effects from both studies, across all treatments arms, that were reported at a frequency greater than 5%. **Importantly, there were no surprises to this list. The most commonly reported side effects were dry mouth, tingling sensation, constipation, upper respiratory infection, and altered taste. The majority of the events were mild**.
>
> The combined EQUIP and CONQUER discontinuation rate is presented in slide 29. Clear measures of drug tolerability are study completion rate and discontinuation rate due to side effects. On slide 29, we observed an overall higher study completion rate along with a **low study discontinuation rate due to AEs [adverse effects]**. Also listed on the slide are the reasons for study discontinuation due to AEs that occurred in greater than 1% of patients. **Importantly, no distinct pattern or reason for dropout is seen, as no event occurred in more than approximately 2% of patients.** As shown on the slide, discontinuation for depression associated with Qnexa, at 1.4%, was low, especially considering that 26 to 30% of patients had background of psychiatric disorders.
>
> Since depression and suicidality are a point of emphasis with the FDA, we perform prospective, comprehensive assessments and in-depth review of all safety data associated with these points. On slide 30, the incidence of moderate and

> severe depression, depressed mood, was similar across all three doses compared to placebo, with reports ranging from 1.2% to 1.9%, as compared to 1.7% on placebo. **There were no serious adverse events reported for depression or depressed mood**.
>
> Slide 30 presents our depression analysis involving the PHQ-9 tool. As part of our prospective analysis of depression, we evaluated the risk of depression using the Physicians' Health Questionnaire, PHQ-9, for each patient at every visit. The PHQ-9 is a validated psychometric instrument accepted by the FDA for assessing the presence and severity of depression. Over 38,000 assessments were administered throughout the phase 3 program. **This extensive assessment supports the conclusion that there is no signal for depression. In fact, as compared to baseline, there was significant improvement in depression assessments as measured by improvement in the PHQ-9 scores for Qnexa**.
>
> As shown in slide 32, suicidality was assessed using the Columbia Suicide Severity Rating Scale or CSSRS. This is a tool developed by Columbia University and accepted by the FDA. Assessments were made at each visit, with over 38,000 assessments taken in EQUIP and CONQUER. **The results of the extensive assessments were: no suicides, no suicide attempts, no suicidal behavior; no signal for suicidal ideation. Based on these results, there is no signal for suicidal risk**.
>
> Overall safety assessments is presented in slide 33. We evaluated serious adverse events across both EQUIP and CONQUER, and found that **there were no differences in either total serious adverse events or drug-related serious adverse events between Qnexa and placebo**. There was one death that occurred in the placebo group.
>
> In addition to the safety assessments included in EQUIP and CONQUER studies, several assessments and additional studies have been performed. **Cognitive function testing: no clinically relevant effects seen. Psychomotor testing: studies are completed and no clinically relevant effects have been observed**. In addition, we completed a thorough QT study, and in this study there was no signal for QT prolongation. Finally, **we have completed several drug interactions and special population studies; these studies are complete, and there were no findings of concern.**
>
> [Emphasis added.]

42. Separately, on September 9, 2009, Defendant Wilson was interviewed on the financial news television network CNBC regarding Qnexa's prospects and safety profile. During this public appearance, Wilson described Qnexa's safety profile as "remarkable" and proclaimed the drug's "superior safety."

43. Vivus shares reacted positively to the announced results for Qnexa. In reaction to this announcement, the price of Vivus's stock dramatically jumped by $4.89 per share, or 70%,

in just one day. On that very same day, September 9, 2009, Defendant Wilson sold 200,000 shares for proceeds of $2,245,000.

44. Over the course of the next several months, Vivus presented at many Wall Street-sponsored healthcare conferences at which Vivus management described the "overwhelmingly positive" results of Qnexa's Phase 3 studies. Time and time again, Defendant Wilson described Qnexa's powerful safety results seen in its Phase 3 studies.

45. On September 10, 2009, Defendant Wilson described Qnexa's positive safety profile at Rodman & Renshaw's Global Investment Conference as an "extremely safe" product for the obesity market, stating, in relevant part:

> Let's turn our attention to safety, obviously a big concern here that we wanted to look and **demonstrate a product that was extremely safe for the obesity market**, **and I think that's what you're going to see that we have come up with**...[t]here is nothing in here of concern that we haven't seen in other trials or is not in the label of existing studies. The most frequent adverse events are dry mouth, tingling and constipation. These are patients losing weight, not drinking enough water and they have these most frequent adverse events, but nothing of concern. Most of these adverse events are not related to drug as well as you'll see in a comparison of placebo to active. Okay. This – let's take a look at the serious adverse events that we had in the trial. Total serious adverse events were the same between Qnexa and when we assess the total safety set for EQUIP and CONQUER between Qnexa and placebo. The drug-related SAE's [serious adverse effects] were not different between Qnexa and placebo as well and clearly at a very low level. There was one death in the study and it occurred on placebo. In addition to the assessments that we did with EQUIP and CONQUER, we have completed a number of other studies important to this therapeutic area. We completed a cognitive function, examination and studies with no clinically relevant effects. We did psychomotor testing with no clinically relevant effects. We did thorough QT analysis and no signal for QT prolongation. We did drug interaction studies, no findings of concern and we looked at special populations such as patients with liver and kidney disease and found no findings of concern.
>
> * * *
>
> The drug was well tolerated with completion rates significantly higher than placebo and a compelling risk benefit profile supporting approval, reimbursement and commercial success of this product.
>
> * * *
>
> **[n]o serious adverse events occurred in this study** . . . the drug-related series adverse events were 0.4% for both active and placebo.
>
> * * *

> Yeah, discontinuation rates, I don't know if we presented them in today's slide, but I'd ask you to go look **nothing of concern**, all very low levels of discontinuation under 2% and spread across the whole thing.
>
> [Emphasis added.]

46. On September 11, 2009, Defendant Day described the strong safety profile and continuation rate of Phase 3 study patients taking Qnexa at the Thomas Weisel Partners Healthcare Conference, noting "no signal of any increase in depression," and "no cardiovascular signal to speak of," stating in relevant part:

> Some of the interesting attributes of Qnexa we think that make it certainly unique and provide the safety and efficacy profile that you see have to do with the dosage.
>
> * * *
>
> One of the important and positive outcomes of the trial was the completion rate. For obesity trials that are notoriously difficult to retain subjects in, we saw a significant completion rate which was greater than placebo on our two Qnexa arms, 57 and 59% specifically, compared to a 47 completion rate on our placebo treated subjects.
>
> * * *
>
> So now just to kind of summarize some of the important safety endpoints from these two trials. This fairly detailed slide that I'm presenting here presents both studies, all 2,500 or so subjects on CONQUER and about 1,250 on EQUIP by treatment arm for all adverse events with a incidence of 5% or greater. So these are the adverse events that were more commonly experienced. Overall, the vast majority of these events were mild in nature and didn't affect retention in the study. But the important thing with our adverse event profile in this study is there were no surprises. We saw adverse events that were fairly consistent with what we've seen in the past, we didn't see anything new, and certainly we didn't see a severity, change or difference from other studies that would have raised a concern. All of these effects were generally mild as I mentioned before. The most common events dry mouth, tingling, constipation, altered taste. These are the types of events that we've seen in the past and have been the most frequent type of events that we've seen before.
>
> **So this wasn't obviously our only safety assessment. We've done quite a few safety assessments. Importantly on serious adverse events, we saw very low overall incidents of SAEs in a treatment-emergent or non-causality based assessment, we see a very similar level of SAEs 3.3% both in Qnexa arms as well as placebo. And then when we look at it on a relatedness perspective, all drug related SAE there was no difference between placebo and Qnexa.**
>
> We've also preformed extensive assessments of cognitive. Those are complete with no real signals of any concern there. Psychomotor testing, we performed a standalone study and that study was completed, no clinically relevant effects. We performed a thorough QT study. That study is complete with no QT

prolongation. And finally, to kind of round-off the whole NDA package, we've performed several drug interactions and special populations, and again **no findings of concern.**

* * *

Depression has been a huge area of interest for us. In all of our studies, we included psychometric tools to assess depression PHQ-9, well recognized, well validated tool for assessing depression recommended by the FDA. This was administered to every subject at every visit, about 38,000 times in each trial. And what I can tell you is that **there was no signal of any increase in depression.** Moreover, we saw a significant improvement in PHQ-9 scores overall.

* * *

The drop-out due to AEs across the board, all treatment arms was low and it was low compared to other similarly designed and executed studies in the Phase 3 setting. What we did see was a 9% discontinuation rate due to AEs for placebo. We saw a slightly lower than that for the low dose of Qnexa and we saw 18% discontinuation for the full-dose of Qnexa. So we did see a slightly higher discontinuation on the full-dose Qnexa despite the fact that the overall completion rate on Qnexa was higher than placebo. So what this suggests is that although a few subjects dropped out on – due to adverse events, the vast majority of subjects did complete and the overall discontinuation rate due to adverse events was relatively low. And there were no single events that appeared to be driving the discontinuation rate. The highest frequency of any event was under 2% for discontinuation rate. So there is no real consistent story on what would explain it, just kind of a broad thing.

* * *

Some of the reasons for dropout were insomnia, for example. This is a pretty common occurrence. It's associated with phentermine. And again, I think it was about 1.5%, accounted for 1.5%. But again there is a whole list of reasons and nothing emerges.

* * *

We did have a few dropout for constipation. Fortunately, constipation, tingling and dry mouth which are reasons for discontinuation, all three of these are well managed with adequate hydration. In the frequency or the rate of weight loss that many of these patients experienced on Qnexa often they become dehydrated and this exacerbates some of the symptoms. So many of the more successful investigators were really good at advising and counseling the patients to keep themselves adequately hydrated.

* * *

Heart rate, there was real – there was no signal there of any clinical relevance. The difference between mid and low dose versus placebo were 0 to 0, no increase at all. The full-dose had one millimeter, I mean, one beat per minute increase in heart rate. Now the reason what we're learning on the heart rate effect is, we saw a significant drop in blood pressure and a one beat per minute on average increase in the presence of the significant change in systolic and diastolic kind of the line . . . ran extensive cardiovascular assessments. We ran a standalone QT study

> which all of that was assessed. And **there is no cardiovascular signal to speak of**. And in the presence of a blood pressure drop that we're seeing with this treatment, one beat per minute increase which has **no statistical or clinical significance isn't something that is of concern or of issue**. In our previous Phase III study we actually saw a reduction in heart rate. So it's not even a consistent effect.
>
> [Emphasis added.]

47. On March 8, 2010, Vivus hosted a conference call to announce Q4 2009 earnings results. Defendants once again brushed aside safety concerns regarding Qnexa's safety profile when questioned by analyst Mike King of Merriman:

> **<Q - Mike King>: [g]iven the sort of political sensitivity and very focused – FDA is very focused on safety issues, why should investors have confidence that Qnexa will gain approval on a first cycle review?**
>
> <A - Leland F. Wilson, Chief Executive Officer>: **The first thing I would say is that we are very confident that Qnexa will be approved on the PDUFA data**. And as you know we have had two products approved on the PDUFA data here at VIVUS and have some credibility I think in speaking to that matter. Now specifically concerning the product, with the FDA it's all about risk benefit profile. And as you know obesity is now known as one of the most devastating diseases we have in this country, cost associated with or in excess of $150 billion a year. And to our knowledge we have the state-of-the-art therapy for the treatment of obesity. I think clearly everyone recognizes the efficacy of Qnexa. Now speaking specifically at the safety considerations here, as you know, Mike, we have expended considerable effort and time trying to meet all of the possible targeted medical event issues that could come up. Things such as the neurologic and psychological aspects of it was our test with PHQ-9, C-CASA suicidality and all those things. We have completed them all under an SPA using the latest tools possible and **we are extremely confident of the outcome**, and I think we've been very forthcoming in disclosing all the data that we have on a top line basis for the safety consideration. **So, the view that we have is this drug is remarkably safe**, clearly there are three doses that has allowed the physician to titrate to a specific patient based upon their tolerance for the drug and clearly even the mid dose had results that achieved greater weight loss than to my knowledge any previous therapy that has been submitted to the FDA...[S]o Peter [Tam], if you have a comment?
>
> <A - Peter Y. Tam, President>: [w]hat we are using is, again is a combination of low doses of two already approved drugs which I certainly feel very comfortable with given the millions of years of patient experience on these two drugs. So, we are very, very confident that the FDA would be able to reach a decision hopefully quickly. We are working with the division right now to answer the questions and we believe that the FDA is really reviewing this in a very expedited – not an expedited review, but they are currently doing their job and we are really glad to see that.
>
> **<A - Leland F. Wilson, Chief Executive Officer>**: Yeah, I would just comment further on what Peter said. **I think a lot of people failed to understand that this submission is done under a 505(b)(2) submission, which relies in part on the**

> **safety that is demonstrated by the two previous approved drugs. And this goes a long ways towards making people comfortable with the safety profile of the drug. As Peter mentioned, there is more than five million patient years of history with these drugs on the market, both are very large selling drugs in the marketplace. And I would also comment that there is not one event in our clinical program that is not in the label for both – for either phentermine or topiramate in the marketplace. So, there were no surprises in our entire clinical program**. I think the only surprises were the dramatic weight loss and because of the reduction in doses that we used over the market products, a reduction in the side-effect profile.
>
> [Emphasis added.]

48. Defendant Wilson then spoke about Qnexa's cardiovascular issues and whether the FDA will require a further "outcome study" of Qnexa's cardiovascular effects prior to approval. Defendant Wilson and Peter Y. Tam, Vivus director of clinical and corporate development, fielded questions from analyst Jason Butler of JMP Securities:

> **<Q - Jason Butler>**: Hi, thanks for taking the question. I had a question relating to the cardiovascular risk. . . . in the run up to the Qnexa NDA submission and in the short time since, has the FDA's communications with you over the requirements to assess cardiovascular risk changed in any way?
>
> <A - Leland F. Wilson, Chief Executive Officer>: No, and in fact we have written communications with the FDA concerning the need for an outcome study. No need – **there is not a need for an outcome study for the treatment of obesity. And so that's been reaffirmed on several occasions in writing from the FDA to us. So we're comfortable with that**. Now that doesn't mean the FDA can't change their mind at any point. The second one that I think is important to consideration [sic] here too, I don't know of a drug that has ever demonstrated an improvement in all cardiovascular and metabolic endpoints that we have seen with Qnexa in these trials. So it speaks highly towards the potential cardiovascular benefits that we've seen – that can be seen with this drug, and I'll ask Peter to comment if he has any other comments on this.
>
> <A - Peter Y. Tam, President>: **So there is nothing here that we believe would trigger an FDA's change of mind in requiring a cardiovascular safety study.**
>
> [Emphasis added.]

49. Defendant Wilson later reiterated his confidence in Qnexa and underscored the importance of the upcoming FDA review process to Vivus's business prospects:

> Again, 2009 was pretty remarkable, but we're looking at 2010 as being potentially even more remarkable, clearly to have a positive panel for Qnexa and to have the approval on the PDUFA date would certainly trump having successful Phase III data that we had last year. So we're looking for a great 2010, someone likened it, or somebody asked me one time, are you nervous or scared? And I said, no I'm probably overconfident, but I'm anxious. **This is our Super Bowl, our**

> **Olympics, et cetera and we're well prepared**. We want to go to the advisory panel, we want to defend our product. **And we believe that the data is – justifies approval on the PDUFA date, and feel strongly about that. So we're ready to go**. And we're going to even be more ready by the time it happens, which will likely have an advisory panel in September, is my opinion, and we'll be ready to go. **So very confident**. And so, appreciate everybody's support, and **it's going to be a great year**.
>
> [Emphasis added.]

50. On May 3, 2010, Vivus hosted a conference call to announce Q1 2010 earnings results. Defendant Wilson once again touted Qnexa's "outstanding" cardiovascular-related data, stating:

> [W]e feel very strongly, as you know, that the cardiovascular benefits of this drug are really outstanding. And so **we're anxious to present our cardiovascular data. It is outstanding**."
>
> [Emphasis added.]

51. During the May 3, 2010, conference call, Defendant Wilson made the following statements regarding Qnexa's psychiatric adverse effects:

> We have presented all the data that we have on our psychiatric AEs to this point. I mean, clearly, we have probably the most thorough and complete look at – of both depression and suicidality of any product that's ever been through the FDA through the Phase 3 program. **And clearly, we really have a zero indication of any suicidality.** When you look at the PHQ-9 test scores, we actually have a slight improvement on treatment. If you look at quality of life, we have an improvement of every major – of every domain that is tested. Now the one area that we have focused on is the dropout rate for patients on depression, and as we have previously presented to you that the dropout rate is higher on the high dose, but that dropout rate, the depression that was there, was primarily mild and manageable and resolved in the majority of cases while still on the drug and still on the study. So we think we have a very thorough and very convincing review of the psychiatric adverse events and we're really very confident that we're in very good shape here. Remember now, as I always like to say, when you talk about the psychiatric adverse events, you're talking about topiramate in general. And so the doses that we use are very low compared to the approved doses of topiramate and the experience in the marketplace now. And then we have the counterbalancing activity, the complementary pharmacology of phentermine, which is really I think helps to ameliorate some of those side effects. And so we have just done an A to Z look at this and really in my view there is really nothing here to report."
>
> [Emphasis added.]

52. Defendants' statements in paragraphs 36 to 52 above, were materially false and misleading because, contrary to the repeated and express trumpeting of Qnexa's safety profile:

(a) the studies conducted by Vivus and submitted to the FDA Panel could not support FDA Panel approval for Qnexa's use to treat obesity as a chronic condition, and longer-term clinical studies would be needed to determine whether Qnexa was safe for its intended use to treat chronic obesity;

(b) the trial results showed significant and worrisome adverse effects of the type that scuttled approval for other obesity drugs, including: increased risk of suicide, cardiovascular events, and birth defects;

(c) four to seven times as many patients taking the highest dose of Qnexa, compared to patients taking lower doses or placebos, dropped out of the study because of adverse side effects such as anxiety, sleep disorders, or depression;

(d) Qnexa would likely receive a "Pregnancy Category X" label from the FDA due to birth defects (teratogenicity) risk, instead of the proposed "Pregnancy Category C" label, thereby potentially eliminating a huge swath of potential Qnexa customers.

53. As a result of Defendants' false and misleading statements, Vivus's stock traded at artificially inflated prices during the Class Period. Such inflated stock prices permitted top Vivus officers/directors to sell shares of their Company stock at inflated prices for proceeds of over $3.6 million. However, after the above adverse news hit the marketplace, the Company's shares were hammered by massive sales, sending them down 60% from their Class Period high.

THE TRUTH BEGINS TO EMERGE

54. On July 15, 2010, the FDA Panel held a hearing to review Qnexa. The FDA Panel acknowledged that Qnexa resulted in "significant" weight loss, but voted against recommending Qnexa based on concerns over potential safety issues relating to serious adverse effects; such as the unknown cardiovascular impact, or negative psychological effects, such as depression and suicide; debated usage by pregnant women due to the potential for birth defects; and the unknown impact of long-term use beyond the 56-week clinical study period. The FDA

Panel voted 10-to-6 in the negative on the question of whether the "overall risk-benefit assessment of Qnexa is favorable to support approval." The FDA usually follows its panel recommendations, although it is not required to do so.

55. The ten FDA Panel committee members voting against approval included: Dr. Bersot, Dr. Burman, Dr. Cragan, Dr. Flegal, Dr. Heckbert, Dr. Morrato, Dr. Proschan, Dr. Thomas, Dr. Weide, and Dr. Capuzzi.

56. Dr. Morrato explained her rationale for voting against recommending Qnexa for FDA approval as follows:

> My concerns were the public health consequences, given the long list of safety risks that were listed for the drug, and the strong pent-up market demand for effective weight loss pharmacotherapy. That is, **the drug will be used by 5 millions of patients over long periods of time, far exceeding the label indications for use and duration of clinical experience that we have...[i]t's chronic disease requiring chronic treatment**. And while it's always challenging when individual patients have personal success stories, I had to ask myself, to balance against the initiating a huge public health experiment...[s]o I erred on no.
>
> **I agree also with the maternal health team's recommendations. If it is to be approved, it would be a category X, and that there be attention made to really think through the development and pretesting of the medication.**
>
> [Emphasis added.]

57. Dr. Proschan explained his rationale for voting against recommending Qnexa for FDA approval as follows:

> I voted no . . . [P]art of my reasons was that **a lot of these potential problems are sort of brain-related, depression, anxiety, memory, cognitive**. And that always makes me worry a little more than with other kinds of problems, although I think there were other problems that certainly were brought up that **I don't think we have enough data to really be able to say whether they are serious issues or not...when you only do a one-year trial, to me I'm not willing to make that leap that in another year, there might not be problems that revealed that these are very serious and they don't go away.**
>
> [Emphasis added.]

58. Dr. Burman explained his rationale for voting against recommending Qnexa for FDA approval as follows:

> I voted no . . . **the medication has serious potential adverse effects, including potential teratogenicity, increased suicidal ideation, cognitive issues,**

> **decreased bicarb, tachycardia, and possible renal stones. Some of these side effects are serious and could be life-threatening, and they have to be weighed against the potential of a relatively modest weight loss and its long-term health benefits. <u>It is difficult if not impossible to weigh these issues since the clinical studies are only for about a year and these medications, if approved, will be used for a much longer time frame in a much wider population</u>.**
>
> The question remains open in my mind whether it is worthwhile to approve a medication for moderate weight loss when it has significant potential issues.
>
> [Emphasis added.]

59. As Dr. Burman highlighted, potential teratogenicity and pregnancy category labeling was also extensively discussed by the FDA Panel. The pregnancy category of a pharmaceutical agent is an assessment of the risk of fetal injury due to the pharmaceutical, if it is used as directed by the mother during pregnancy. Vivus requested a birth-defects designation of "pregnancy category C," which denotes "animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks." However, according to documents submitted to the panel for review (the "FDA Memo") the Company's proposed labeling for Qnexa included pregnancy warnings and precautions that are typically associated with a pregnancy category D or X drug. Category D or X labeling indicates either: "there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks," or "studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits," respectively. The FDA Memo noted that Vivus's proposed labeling could be confusing to physicians and patients of child-bearing age, and that such confusion was a serious concern because of the "large potential" for women to become pregnant while taking the drug, thereby triggering the birth defect concerns. The FDA Memo recommended that Qnexa be labeled as "pregnancy category X," the strongest label possible, indicating that the risk of using of Qnexa during pregnancy "clearly

outweighs any possible benefit," and also recommended that Vivus's labeling include risk evaluation and mitigation strategies (REMS) for patients in case of accidental pregnancy by Qnexa users.

60. Dr. Flegal explained her rationale for voting against recommending Qnexa for FDA approval as follows:

> I also voted no . . . I think my views -- I think it was both colored, maybe, by our experience with Avandia and the safety concerns that we should deal with them before rather than afterwards...**[t]his is like a public health experiment, a large gamble**. And I think widespread usage even in inappropriate populations is difficult to prevent. **We have one-year information, but this drug will likely be used for a long time**. It really addresses surrogate endpoints, and there's minimal information on subgroups, even, like sex and ethnic groups. I think we need more data. . . [A]nd I think that the risk management is a very difficult challenge, and that we need more information and research on how to really monitor this, how to control access.
>
> [Emphasis added.]

61. Dr. Thomas explained his rationale for voting against recommending Qnexa for FDA approval as follows:

> I voted no. And just to preface, before I moved to Henry Ford, for six years I was the medical director of a weight management program at the Brigham, taking care of thousands of patients with obesity . . . **[T]he concerns we have are with safety.** And as previously mentioned, we want to make sure we don't avoid a situation where, five years from now, we're back from an advisory meeting considering safety issues. So there's a few things that I think have to be addressed, and I think it's best that these are addressed before approval, or at least started before approval so that they can be finished soon after the medication is released.
>
> The first is cardiovascular disease . . . I think we should start a cardiovascular trial to look at outcomes in a higher risk population before release so we have the data within two to three years of release of the medication.
>
> The second thing is I'm very concerned about bone health . . . [T]his medication, because of the acidosis, could affect both spectrums of bone health, peak bone mass in the younger generation -- because peak bone mass is developed through the mid-20s -- and then osteoporosis or fracture risk in the older subjects. I think this data could be accumulated as part of some of these studies that are done for safety because they'll have large numbers to tell, and hopefully we'll also have fracture data from the sponsor at a later point.
>
> The third thing is the sponsor used a restricted fat diet, not a low carbohydrate diet. Most patients, when they're going to use this, will pick a diet of their own, in spite of what we tell them. So we do need to have some real world data of what

> happens when people are on a low fat diet versus a high fat diet...[S]o I think some data on that would be important to know what happens with acidosis.
>
> We do need more information about suicide risk. It took 10- or 12,000 patients for rimonabant to have that signal to be really clear. The meta-analysis also needed a lot of patients with topiramate. So I think as the course of data is being obtained for these other outcomes, like cardiovascular disease, that data can also be obtained in terms of depression and suicidal ideation.
>
> Then finally, **I think we have to get away from the concept of usage for a short term. Obesity is a chronic disease**. Blood pressure is a chronic disease. I would never go to someone who has high blood pressure and say, your blood pressure is normal; now we stop all your medications; see you in a year. But with obesity, we view it that way. **So we have to look at the long-term safety of these medications so we can prevent weight regain.**
>
> [Emphasis added.]

62. Dr. Bersot explained his rationale for voting against recommending Qnexa for FDA approval as follows:

> I'm the second of the doubting Thomases . . . [W]e need more evidence in the high risk cardiovascular disease patient.

63. Dr. Weide explained his rationale for voting against recommending Qnexa for FDA approval as follows:

> I voted no . . . you have to say, tell me what's going to happen with my patients as I allow them to stay on the medication [indefinitely]. And that's one of the things that bothers me. If, with a year's trial, you have double the depression risk and you have some cardiovascular questions, I would like to see it extended. I would like to see the at-risk population be sicker, if you will, so that we can find out whether or not these safety concerns are going to be a major issue. I would agree, **I am really sick of taking medicines off of the market after they've been on a year or two because we've identified something that we didn't know about.** And that really is some of what has given the FDA a reputation outside in the public.
>
> * * *
>
> We do have a responsibility to protect the public at large, and that means, although as much as I feel for the people who want this drug and want to lose weight, we have to protect the population at large. **And I think we just need longer term data with the people who are really going to be using it out there rather than a select group of patients in fairly good health.**
>
> [Emphasis added.]

64. Dr. Cragan explained her rationale for voting against recommending Qnexa for FDA approval as follows:

> I voted no . . . in the end, **I couldn't really justify widespread use with the reproductive outcomes concerns that we have.** And as I listened to the panel members discuss the other adverse events, it actually raised my level of concern rather than lessening it.
>
> [Emphasis added.]

65. Dr. Susan R. Heckbert explained her rationale for voting against recommending Qnexa for FDA approval as follows:

> I voted no . . . obesity is very difficult to combat, the medications that are used to treat it are often very strong medications with a variety of different effects. We've talked here about how these two medications interfere with a number of different biological pathways . . . **we have a number of signals of adverse effects that really can't be ignored that need more exploration. And the ones I'm most concerned about are the suicidality risk, the potential for cardiovascular risk based on the mechanism of action of these drugs and the heart rate signal, and of course the teratogenicity.** [It won't] be possible to fully answer that teratogenicity question with clinical trials. But I think we do need more information about it as well as the other serious endpoints that I mentioned.
>
> [Emphasis added.]

66. Panel members indicated that chronic use would require longer-term studies of approximately five years would be necessary to satisfy their safety concerns relating to chronic use. Dr. Proschan, a mathematical statistician for the National Institutes of Health, noted that if there was a "longer follow-up" he would have voted yes and gave the following example to prove his point that one year of data was inadequate to approve Qnexa for chronic use:

> I don't feel comfortable with one year follow-up. In clinical trials, people often say, well, how do you know that it won't cause cancer in 15 years? The answer is, we don't know. We do five-year trials. We don't know whether it might cause cancer in 15. But when you do a one-year trial, to me, I'm not willing to make that leap in another year, there might not be problems that revealed that these are very serious and they won't go away.

67. Dr. Flegal, Senior Research Scientist of the National Center for Health Statistics of the Centers for Disease Control and Prevention, voiced similar concerns, suggesting that five-

years of data would give a better indication of the safety effects of Qnexa. *See id.* at p. 355, lines 19 through p. 356 line 1.

68. In a statement made on July 15, 2010, Defendant Wilson stated that the Company was disappointed by the FDA Panel's decision but said Vivus would work with the FDA in advance of the October 28, 2010, deadline to rule on Qnexa's NDA.

69. In reaction to Vivus's July 15, 2010, disclosure, the price of Vivus's common stock plummeted, from a closing price of $12.11 per share on July 15, 2010, to a closing price of $5.41 per share on July 16, 2010, a one-day drop of 55% on unusually heavy trading volume of over 42 million shares.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

70. At all relevant times, the market for Vivus's common stock was an efficient market for the following reasons, among others:

(a) Vivus's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Vivus filed periodic public reports with the SEC and the NASDAQ;

(c) Vivus regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Vivus was followed by several securities analysts employed by major brokerage firms who wrote reports, which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

71. As a result of the foregoing, the market for Vivus's common stock promptly digested current information regarding Vivus from all publicly available sources and reflected such information in Vivus's stock price. Under these circumstances, all purchasers of Vivus's common stock during the Class Period suffered similar injury through their purchase of Vivus's stock at artificially inflated prices and a presumption of reliance applies.

ADDITIONAL SCIENTER ALLEGATIONS

72. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Vivus, their control over, and/or receipt and/or modification of Vivus's allegedly materially misleading misstatements and/or their associations with the Company, which made them privy to confidential proprietary information concerning Vivus, participated in the fraudulent scheme alleged herein.

LOSS CAUSATION

73. By misrepresenting, *inter alia*, the Company's prospects for its new experimental drug Qnexa, the Defendants presented a misleading picture of Vivus's business and prospects. Thus, instead of truthfully disclosing during the Class Period that Qnexa raised certain important safety concerns, Defendants constantly assured investors that Qnexa was safe and effective.

74. These claims caused and maintained the artificial inflation in Vivus's stock price throughout the Class Period and until the truth was revealed to the market.

75. On July 15, 2010, the FDA panel voted against approving Qnexa, finding that the benefits of the drug did not outweigh the risks associated with the drug, causing Vivus's stock price to drop $6.70 per share, or 55%, in one day.

76. As a direct result of public revelations regarding Qnexa's safety issues, Vivus's stock price fell more 60% from its Class Period high, from $13.68 per share on May 18, 2010, to close at $5.41 per share on July 16, 2010. This drop removed the inflation from Vivus's stock price, causing real economic loss to investors who had purchased the stock during the Class Period.

NO SAFE HARBOR

77. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Vivus who knew that those statements were false when made.

FIRST CLAIM
Violation Of Section 10(b) Of
The Exchange Act And Rule 10b-5
Promulgated Thereunder Against All Defendants

78. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

79. During the Class Period, Vivus and the Individual Defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (b) artificially inflate and maintain the market price of Vivus's securities; and

(c) cause Plaintiff and other members of the Class to purchase Vivus's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

80. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Vivus's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

81. In addition to the duties of full disclosure imposed on Defendants as a result of their making of affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. Sections 210.01 *et seq.*) and Regulation S-K (17 C.F.R. Sections 229.10 *et seq.*) and other SEC regulations, including accurate and truthful information with respect to the Company's operations, financial condition and earnings so that the market price of the Company's securities would be based on truthful, complete and accurate information.

82. Vivus and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Vivus as specified herein.

83. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Vivus's value and performance and continued substantial growth, which included the making of, or the

participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Vivus and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Vivus's securities during the Class Period.

84. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (a) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period; (b) the Individual Defendants were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; and (c) the Individual Defendants were aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

85. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Vivus's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

86. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Vivus's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of

Vivus's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Vivus securities during the Class Period at artificially high prices and were damaged thereby.

87. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known of the true financial condition and business prospects of Vivus, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Vivus securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

88. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

89. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation Of Section 20(a) Of
The Exchange Act Against the Individual Defendants

90. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

91. The Individual Defendants acted as controlling persons of Vivus within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to

influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

92. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

93. As set forth above, Vivus and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions each as a controlling person, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Vivus's and the Individual Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, designating Plaintiff as lead Plaintiff and certifying Plaintiff as class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as lead counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: November 2, 2010

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CERTIFICATION OF PROPOSED NAMED PLAINTIFF

I, Merle Kovtun, certify that:

1. I have reviewed the complaint, adopt its allegations and authorize its filing by Milberg LLP.
2. I authorize Milberg LLP to act on my behalf in this matter for all purposes.
3. I did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.
4. I am willing to serve as a representative party who acts on behalf of a class, including providing testimony at deposition and trial, if necessary.
5. I represent and warrant that I am authorized to execute this Certification on behalf of the purchasers of the subject securities described herein (including, as the case may be, myself, any co-owners, any corporations or other entities, and/or any beneficial owners).
6. I will not accept any payments for serving as a representative party on behalf of the class beyond the purchaser's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.
7. I understand that this is not a claim form, and that my ability to share in any recovery as a member of the class is unaffected by my decision to serve as a representative party or Named Plaintiff.
8. I have made no transactions during the class period in the debt or equity securities that are the subject of the action except those set forth in this certificate.
9. The number of shares or other securities of Vivus, Inc. (VVUS) I held immediately **BEFORE** the first day of the Class Period referenced in the relevant complaint (if any) was: _____ and the type of securities was (check one):
   ☒Common Stock ☐Bonds ☐Preferred Stock ☐Call ☐Put
10. I have listed below all my transactions in the securities of Vivus, Inc. (VVUS) **DURING** the Class Period referenced in the complaint as follows:

Type of Security (Common stock, Preferred Stock, Calls, Puts or Bonds)	**Purchase/Acquisition** or **Sale/Disposition**	**Quantity**	**Trade Date** (mm/dd/yy)	**Price per Share/Security ($)**
SEE ATTACHED SCHEDULE A				

These securities were acquired or held in (check all that apply): ❑ General (non-retirement account)
❑ Merger/acquisition/distribution ❑ Gift ❑ IRA ❑ Employer-sponsored plan (401k, 403b, etc.)

11. I made the following sales of securities of Vivus, Inc. (VVUS) during the **90-day period AFTER** the Class Period referenced in the complaint:

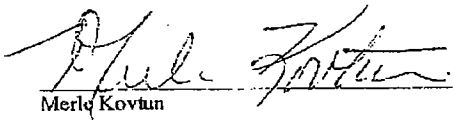
Sales

Type of Security (Common stock, Preferred Stock, Calls, Puts or Bonds)	**Quantity**	**Trade Date** (mm/dd/yy)	**Price per Share/Security ($)**
See attached Schedule A.			

12. During the three years prior to the date of this Certification, I have not sought to serve and I have not served as a representative party for a class in an action filed under the federal securities laws, except as described below (if any): None

I declare under penalty of perjury, under the laws of the United States, that the information entered is accurate.

Executed this 8th day of October 2010



Merle Kovtun

Schedule A
Merle Kovtun's transactions in
Vivus, Inc. (Nasdaq: VVUS)

Purchase(s):	**Date**	**Shares**	**Price**
	09/10/09	**5,000**	12.1300
	10/12/09	**2,000**	10.2400
	11/05/09	**2,000**	7.3800
Sale(s):			
	03/24/10	4,000	9.5100
	06/22/10	750	10.1800
	07/01/10	1,750	9.1000
Option Trading			
Sept 15 Calls Sale	05/24/10	15	2.9000
Sept 15 Calls Purchase	07/01/10	15	1.0500
Dec 9 Calls Sale	07/01/10	15	3.7000